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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,045	06/24/2003	Michelle M. Hanna	2072.0010003	8156
26111 7590 10/19/2007 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER KIM, YOUNG J	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 10/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/602,045	Applicant(s) HANNA, MICHELLE M.	
	Examiner Young J. Kim	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-12,85-97,100,101,115-129,135 and 137-156 is/are pending in the application.
- 4a) Of the above claim(s) 90,101 and 137-139 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12,85-89,91-97,100,115-129,135 and 140-156 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The present Office Action is responsive to the Amendment received on July 6, 2007.

Oath/Declaration

The objection made to Oath/Declaration, made in the Office Action mailed on November 9, 2006 is withdrawn in view of Applicants' arguments presented in the Amendment received on July 6, 2007 and May 9, 2007.

Rejection, Maintained

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on November 9, 2006 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on July 6, 2007 (and May 9, 2007 submission) have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments" section.

The Rejection:

Claim 6 is indefinite for using a trademark, "primase®." Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is

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used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a polymerase and, accordingly, the identification/description is indefinite.

Response to Arguments:

Applicants' arguments with respect to the present rejection has been noted.

Regardless of the argument that Applicants' reference to the term, "primase," is understood to be different from that which is trademarked (page 13, bottom paragraph to page 14, top paragraph), the usage of the term still embraces the embodiment, that is, the use of an enzyme that is trademarked. If Applicants want to claim an embodiment drawn to the use of a primase, that is different from the enzyme that is currently trademarked, then Applicants are encouraged to use a term that generically defines the enzyme without the use of the term, (such as "an RNP polymerase which is a product of dnaG gene," provided that Applicants have support for such a language.

The rejection is maintained therefore.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-3, 6-10, 12, 85-87, 91, 92, 115-117, 120-123, 125-128, 135, 140-142, and 144-147 35 U.S.C. 102(b) as being anticipated by Lu et al. (U.S. Patent No. 5,571,669, issued

November 5, 1996), made in the Office Action mailed on November 9, 2006 is maintained for the reasons already of record.

In addition, the present rejection includes the rejection of claims 151-156, which were added by Applicants' amendment.

Applicants' arguments presented in the Amendment received on July 6, 2007 and May 9, 2007 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments" section.

The Rejection:

As pointed out in *In re Mott*, 190 U.S.P.Q. 536 (CCPA 1975), "Claims must be given broadest reasonable construction their language will permit in ex parte prosecution, and applicant who uses broad language runs the risk that others may be able to support the same claim with a different disclosure."

While the instant invention does not appear to be drawn to that which is disclosed by Lu et al., the claims are broad and thus embraces embodiments which are anticipated by Lu et al. for the following reasons.

Lu et al. disclose a method of transcriptional sequencing method, wherein the method comprises the steps of incubating a target polynucleotide (target DNA template; column 5, lines 47-48) with an RNA primer (thus an initiator; column 5, lines 51-52) and extending said RNA primer/DNA template chimera with an RNA polymerase (column 5, lines 55-56), wherein the method incorporates, during transcription reaction, one or more nucleotide triphosphate analog reactants (column 5, lines 60-62), wherein said nucleotide triphosphate analog reactants is explicitly contemplated as being a chain terminator (3' dideoxynucleotide triphosphate; column 18, lines 58-

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62), for the explicit purpose of sequencing reaction (column 18, lines 62-23; column 19, lines 1-8), thereby clearly anticipating instant claims 1-3, 8, 12, 85, 86, 115, 116, 125-128, 140, 145, and 146.

With regard to claims 3, 87, 117, and 147, the artisans disclose the use of radio-labeled RNA primers (column 8, lines 34-35) and radio-labeled nucleotide triphosphates ³²γ GTP (column 15, line 3).

With regard to claims 6, 120, 141, and 142, the RNA polymerase is an RNA-dependent RNA polymerase, or a DNA-dependent RNA polymerase (column 4, lines 20-39).

With regard to claims 7 and 121, the RNA polymerase is selected from T7, T3, SP6 RNA polymerase, and “the like.” (column 6, lines 61-67).

With regard to claims 9, 91, 122, and 135, the RNA primer employed in the method is at least 1 nucleotide long (column 5, lines 50-51).

With regard to claims 10, 92, and 123, it is asserted that the transcription product being sequenced is at least 2 nucleotides long.

With regard to claim 144, the artisans also contemplate reverse transcription reaction (column 5, lines 32-35).

Therefore, Lu et al anticipate the invention as claimed.

Response to Arguments:

Applicants contend that the instant invention is drawn to a method involving an *abortive* process (page 14, Response received on May 9, 2007).

This argument is not found persuasive because the claimed method does not recited that the synthesis is halted by abortive process, but by termination process (i.e., inclusion of the terminator in the synthesis process).

If Applicants are contending that the inclusion of a terminator into a growing strand of synthesized product, then it is respectfully submitted that Lu et al. also “aborts” their synthesis by the incorporation of a terminator, 3’ dideoxynucleotide triphosphate (see column 18, lines 58-62).

Applicants also attempt to draw a distinction between a generic term, “initiator” and the term, “primer.”

It is respectfully submitted that the two terms are not distinguishable as a primer also “initiates” a synthesis. Absent an explicit definition in the specification or recited in the claims, primer would clearly meet the limitation imposed by the generic term, “initiator.”

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 4, 5, 88, 89, 100, 118, 119, and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu et al. (U.S. Patent No. 5,571,669, issued November 5, 1996) in view of Sasaki et al. (PNAS, 1998, vol. 95, pages 3455-3460; IDS ref # AS21¹) made in the Office Action mailed on November 9, 2006 is maintained for the reasons already of record.

Applicants’ arguments presented in the Amendment received on May 9, 2007 and July 6, 2007 solely rely on the arguments which were already addressed above.

Therefore, the rejection is maintained for the reasons already of record.

¹ IDS received on December 13, 2004.

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The Rejection:

The teachings of Lu et al. have already been discussed above.

Lu et al. do not explicitly disclose that fluorescent labels be employed in their method.

Sasaki et al. disclose a method of sequencing a DNA via use of RNA polymerase, wherein the method employs chain terminating dideoxy nucleotides that are fluorescently labeled (page 3455, 2nd column, bottom paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lu et al. with the advantages offered by Sasaki et al. to arrive at the claimed invention because by doing so, one of ordinary skill in the art would have been able to take advantage of environmentally-safe and more sensitive labels which are commonly employed in a sequencing reaction and/or detection reactions as employed by Sasaki et al.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

The rejection of claims 11, 93, 94, 96, 97, and 124 under 35 U.S.C. 103(a) as being unpatentable over Lu et al. (U.S. Patent No. 5,571,669, issued November 5, 1996) in view of Kramer et al. (U.S. Patent No. 5,503,979, issued April 2, 1996; IDS ref# AA³) made in the Office Action mailed on November 9, 2006 is maintained for the reasons already of record.

Applicants' arguments presented in the Amendment received on May 9, 2007 and July 6, 2007 solely rely on the arguments which were already addressed above.

Therefore, the rejection is maintained for the reasons already of record.

The Rejection:

The teachings of Lu et al. have already been discussed above.

Lu et al. do not explicitly disclose that the method comprise incubating the transcripts to a target site probe specific for a region on said target-polynucleotide, or that a detection comprises hybridizing a complementary sequence to the synthesized transcripts, immobilizing the target sequence, immobilizing by hybridization to a capture probe.

Kramer et al. disclose a method of employing a capture probe to immobilize the target nucleic acid which would undergo further replication (Figure 8; column 10, lines 55-67).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to employ the well-known technique of employing capture probes to first immobilize the target nucleic acid prior to further reaction, as evidenced by Kramer et al., to the teachings of Lu et al. thereby arriving at the claimed invention because by doing so, one of ordinary skill in the art would have been able to separate the target nucleic acid which are not hybridized to the capture probe to avoid false positive signals from the assay of said artisans. As expressed by Kramer et al., such technique is well known in the art:

“The unhybridized recombinant RNA molecules (*i.e.*, *target nucleic acid*) may be separated from those that are unhybridized to the oligo- or polynucleotides of interest by employing techniques and skills which are well-known in the art. In the usual case, with the recombinant RNA molecule hybridized to the oligo- or polynucleotide of interest, which in turn is bound to a solid support, such separation is readily accomplished by simple washing which does not significantly disrupt the connection to the solid support.” (column 12, lines 54-60).

MPEP, at 2143.02, states that the prior art can be modified or combined to reject claims as obvious as long as there is a reasonable expectation of success. Therefore, it is clear that one of ordinary skill in the art would have had a reasonable expectation of success at employing such well-

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known technique of Kramer et al. for the obvious advantage of separating the target nucleic acids from other nucleic acids which could give false positive results.

Therefore, for the above reasons, the invention as claimed is *prima facie* obvious over the cited references.

The rejection of claim 95 under 35 U.S.C. 103(a) as being unpatentable over Lu et al. (U.S. Patent No. 5,571,669, issued November 5, 1996) in view of Kramer et al. (U.S. Patent No. 5,503,979, issued April 2, 1996; IDS ref# AA³) as applied to claims 11, 93, 94, 96, 97, and 124 above, and further in view of Sasaki et al. (PNAS, 1998, vol. 95, pages 3455-3460; IDS ref # AS21³) made in the Office Action mailed on November 9, 2006 is maintained for the reasons already of record.

Applicants' arguments presented in the Amendment received on May 9, 2007 and July 6, 2007 solely rely on the arguments which were already addressed above.

Therefore, the rejection is maintained for the reasons already of record.

The Rejection:

The teachings of Lu et al. and Kramer et al. have already been discussed above.

Lu et al. do not explicitly disclose that fluorescent labels be employed in their method.

Sasaki et al. disclose a method of sequencing a DNA via use of RNA polymerase, wherein the method employs chain terminating dideoxy nucleotides that are fluorescently labeled (page 3455, 2nd column, bottom paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lu et al. and Kramer et al. with the advantages offered by Sasaki et al. to arrive at the claimed invention because by doing so, one of ordinary skill in

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the art would have been able to take advantage of environmentally-safe and more sensitive labels which are commonly employed in a sequencing reaction and/or detection reactions as employed by Sasaki et al.

Therefore, for the above reasons, the invention as claimed is *prima facie* obvious over the cited references.

The rejection of claims 143 and 148-150 under 35 U.S.C. 103(a) as being unpatentable over Lu et al. (U.S. Patent No. 5,571,669, issued November 5, 1996) in view of Gohara et al. (Journal of Biological Chemistry, 2000, vol. 275, no. 33, pages 25523-25532) made in the Office Action mailed on November 9, 2006 is maintained for the reasons already of record.

Applicants' arguments presented in the Amendment received on May 9, 2007 and July 6, 2007 solely rely on the arguments which were already addressed above.

Therefore, the rejection is maintained for the reasons already of record.

The Rejection:

The teachings of Lu et al. have already been discussed above.

Lu et al. do not explicitly disclose that an RNA-dependent RNA-polymerase is a poliovirus RNA polymerase (claim 143) or that the target nucleic acid is from a virus (claim 148), an RNA virus (claim 149), or that the target nucleic acid is from a bacterium (claim 150).

Gohara et al. disclose a well known fact that poliovirus RNA polymerase utilizes DNA primers (page 25523, 2nd column, 3rd paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to employ any of the well known RNA polymerases in the method of Lu et al., as Lu et al. clearly contemplates transcription of template nucleic acid via use of a DNA primer (see column 4, lines 49-50), one of ordinary skill in the art at the time the invention was made would

have been motivated to employ any of the known RNA polymerases which acts on DNA primers for the purpose of transcriptional sequencing, as disclosed by Lu et al., with a reasonable expectation of success.

With regard to the detection of target nucleic acids, wherein said target is from a virus or a bacterium, it would have been further obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Lu et al. for the purpose of detecting and characterizing the sequences of a virus or bacterium for the well-established benefit of diagnosing infectious agents in patients and samples.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Double Patenting

Rejections, Maintained

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1-12, 85-89, 91-97, 100, 115-136, and 140-150 (in-part) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-17 and 19-27 of copending Application No. 10/425,037 (herein, the '037 application), made in the Office Action mailed on February 22, 2006 is maintained for the reasons of record.

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The instant rejection also includes claims 151-156 as being necessitated by Amendment.

Applicants state, in their response received on May 9, 2007 that the rejection be held in abeyance (page 20, Response).

As no response is made as to why the rejection is improper, the rejection is maintained for the reasons of record.

The rejection of claims 1-12, 85-89, 91-97, 100, 115-136, and 140-150 (in-part) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 136-147 of copending Application No. 10/686,713 (herein, the '713 application), made in the Office Action mailed on February 22, 2006 is maintained for the reasons of record.

Applicants state, in their response received on May 9, 2007 that the rejection be held in abeyance (page 20, Response).

As no response is made as to why the rejection is improper, the rejection is maintained for the reasons of record.

MPEP 804(I)(B)(1), in discussing provisional obviousness-type double patenting, states:

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

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Where there are three applications containing claims that conflict such that an ODP rejection is made in each application based upon the other two, it is not sufficient to file a terminal disclaimer in only one of the applications addressing the other two applications. Rather, an appropriate terminal disclaimer must be filed in at least two of the applications to link all three together. This is because a terminal disclaimer filed to obviate a double patenting rejection is effective only with respect to the application in which the terminal disclaimer is filed; it is not effective to link the other two applications to each other.

As the instant Office Action contains rejections which are substantive, the ODP rejection is properly maintained herein.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

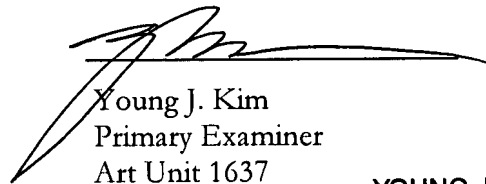
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the

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status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Young J. Kim
Primary Examiner
Art Unit 1637
10/15/2007

**YOUNG J. KIM
PRIMARY EXAMINER**

YJK